

PEEK Customized Cranial Implant Kit

Traditional 510(k)

750 Trade Centre Way
 Suite 200
 Portage, MI 49002
 t: 269 324 5346 f: 877 648 7114
www.stryker.com

SEP 14 2012
stryker®

Craniomaxillofacial

510(k) Summary**Sponsor:**

Stryker Leibinger GmbH & Co. KG
 Boetzinger Strasse 41
 79111 Freiburg, Germany

Proprietary Name:

PEEK Customized Cranial Implant Kit

Common Name:

Customized Cranial Implant

Classification Name and Reference:

21 CFR §882.5320 - Preformed alterable
 cranioplasty plate

Proposed Regulatory Class:

Class II

Product Codes:

GWO

Predicate Devices:

K053199 - Synthes Patient Specific
 Cranial/Craniofacial Implant

K111065 - Stryker Patient Specific Polymer
 Implant

Contact Person:

Manish Patel
 Regulatory Compliance Analyst
 Stryker Craniomaxillofacial
 750 Trade Centre Way, Suite 200
 Portage, MI 49002
 Phone: (269) 389-4271
 Fax: 877-648-7114
manish.patel@stryker.com

Date Prepared:

April 12, 2012

Intended Use:

PEEK Customized Cranial Implant Kit is intended to be used to replace bony voids in the cranial and the craniofacial skeleton.

Indications for Use:

The PEEK Customized Cranial Implant Kit is indicated for filling bony voids in the cranial and craniofacial skeleton in patients 12 years of age and older.

Device Description:

PEEK Customized Implant Kit consists of the PEEK Customized Cranial Implant or the PEEK Customized Craniofacial Implant, the Host Bone Model, and the Design Proposal.

PEEK Customized Cranial Implant:

The PEEK Customized Cranial Implant is a customized patient-specific implant based on CT-data and input by the surgeon. The implant is fabricated from polyetheretherketone (PEEK) and is intended to be used to fill bony voids in the cranial skeleton. It is delivered non-sterile.

PEEK Customized Craniofacial Implant:

The PEEK Customized Craniofacial Implant is a customized patient-specific implant based on CT-data. The implant is fabricated from polyetheretherketone (PEEK) and is intended to be used to fill bony voids in the craniofacial region (orbital rim, zygoma, and adjacent bone). The implant matches the shape and dimensions of the missing bone fragments. It is delivered non-sterile.

The host bone model is provided as a preoperative guide to demonstrate orientation and fit of the PEEK Customized Cranial Implant. The Design Proposal is a presentation of virtual 3-dimensional models of the implant design. The PEEK Customized Cranial Implant is offered in different sizes based on the size of the cranial defect. Depending on the surgeon's preference, the PEEK Customized Cranial Implant may be constructed in varying thicknesses, wall designs, number of dura suture holes and dura suture hole diameters. The PEEK Customized Cranial Implant is fixated to the native bone with

Stryker Neuro, Midface or Upperface self-tapping screws. The PEEK Customized Cranial and Craniofacial Implant Kit is bundled with an online ordering system called “eRequest Lifecycle”, whereby the user can initiate a case request, upload the patient specific image data, download the Design Proposal and approve the implant design.

Technological Characteristics:

The PEEK Customized Cranial and Craniofacial Implant Kit is designed individually on a patient-by- patient basis upon request of the surgeon using a validated “Virtual Implant Design Process” (VIDP). A CT scan received from the health care facility is used to generate a 3 dimensional model of the skull with the defect to be filled. This 3-dimensional model of the skull is then used to design the implant. The design is virtually presented as a Design Proposal, which is then reviewed and approved remotely by the surgeon, and modified if desired. Once the design is approved, the PEEK Customized Cranial and Craniofacial Implant Kit and the Host Bone Model are manufactured and shipped to the health care facility along with a print of the approved Design Proposal. The PEEK Customized Cranial and Craniofacial Implant Kit are offered non-sterile to the customer.

The PEEK Customized Cranial and Craniofacial Implant Kit are similar or identical to its predicate devices in the following technical characteristics:

- **Material:** The PEEK Customized Cranial Implant and the Synthes Patient Specific Cranial/Craniofacial Implant – K053199 are made of the identical medical grade PEEK Optima LT1 from the same supplier, Invibio
- **Design:** The PEEK Customized Cranial Implant and the Stryker Patient Specific Polymer Implant – K111065 are designed using the identical software and Virtual Implant Design Process (VIDP)
- **Sterility:** The PEEK Customized Cranial Implant and the Synthes Patient Specific Cranial/Craniofacial Implant – K053199 are delivered non-sterile to the user
- **Case initiation and data exchange:** The PEEK Customized Cranial Implant and the Stryker Patient Specific Polymer Implant – K111065 use identical systems

for case initiation, uploading of imaging data, downloading of Design Proposal and approval.

Performance Data:

Various performance tests including stability tests, trimming tests, drilling tests, screw insertion tests and screw pull-out tests were performed on the PEEK Customized Cranial Implants and Craniofacial Implants. The results of these tests demonstrated that the PEEK Customized Cranial and craniofacial Implants have mechanical strength comparable to native skull, and do not melt or lose integrity upon burring, drilling and/or screw insertion with recommended burrs, drills and screws. A handling test performed in a Cadaver Lab with surgeons demonstrated that the implants met the user needs and fit the defects.

Substantial Equivalence:

The PEEK Customized Cranial and Craniofacial Implant Kit are substantially equivalent to its predicate devices in regards to intended use, design, materials and operational principle. Further, the performance data confirms that the PEEK Customized Cranial and Craniofacial Implant Kit are safe and effective and performs as well as its predicate devices listed below.

Predicate Devices:

1. Synthes Patient Specific Cranial/Craniofacial Implant – K053199.
2. Stryker Patient Specific Polymer Implant – K111065.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

SEP 14 2012

Stryker Craniomaxillofacial
c/o Mr. Manish Patel
Regulatory Compliance Analyst
750 Trade Centre Way, Suite 200
Portage, MI 49002

Re: K121153

Trade/Device Name: PEEK Customized Cranial Implant Kit
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GWO
Dated: September 5, 2012
Received: September 6, 2012

Dear Mr. Patel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for
Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K121153

PEEK Customized Cranial Implant Kit

Traditional 510(k)

Indications for Use:

510(k) Number (if known): K121153

Device Name: PEEK Customized Cranial Implant Kit

Intended Use:

PEEK Customized Cranial Implant Kit is intended to be used to replace bony voids in the cranial and the craniofacial skeleton.

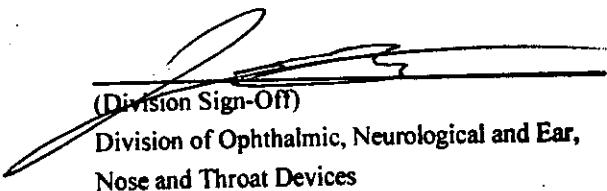
Indications for Use:

The PEEK Customized Cranial Implant Kit is indicated for filling bony voids in the cranial and craniofacial skeleton in patients 12 years of age and older.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K121153